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(54) **Preparation for blood dialysis and method for production thereof.**

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Description

Field of the Invention:

The present invention relates to a preparation for blood dialysis and a method for the production thereof. More particularly, it relates to a uniform powdery preparation for blood dialysis excellent in stability of storage and a method for the production thereof.

Description of the Prior Art:

In the performance of blood dialysis, the patient's blood is purified in the artificial kidney. Inside the artificial kidney, the purification of the blood is effected by keeping the dialytic solution circulated in the artificial kidney, allowing the dialytic solution to contact the blood through the medium of a permeable membrane, and causing the waste matter and water accompanied by the blood to pass into the dialytic solution. The dialytic solution is closely and impartibly related to the improvement of the artificial kidney in performance. The acetate dialytic solution, the leader of the conventional dialytic solutions, is such that owing to the advance of the artificial kidney in quality, the acetic acid allowed to pass from this dialytic solution into the patient's vital organs has gained in quantity and the acetic acid causes the patient to suffer from such displeasing symptoms as headache and hypotension. Thus, it is giving place to the bicarbonate dialytic solution which exerts no appreciable burden upon the patient.

Unlike the acetate dialytic solution, the bicarbonate dialytic solution cannot be prepared as a single-component dope because sodium hydrogen carbonate present therein, on reaction with calcium or magnesium, gives rise to a precipitate. The bicarbonate dialytic solution, therefore, is prepared as a two-component composition comprising sodium hydrogen carbonate (principal solution) and a component containing calcium, magnesium, sodium, etc. (formulating liquid).

The principal component is prepared in the form of powder or solution and the formulating component in the form of solution. The amount of the principal component to be used is in the range of 500 to 1,000 g as powder or 10 to 12 liters as liquid and that of the formulating component in the range of 9 to 12 liters as liquid respectively per patient. In an institute abounding in patients, the work of transferring storage tanks of the dialytic solution exerts a heavy burden on workers. In an institute capable of performing dialysis simultaneously on 20 patients, for example, the dopes of both principal component and formulating component in a total amount enough for 40 patients (about 380 to 480 kg) must be transferred. The institute suffers also from the problem that the transfer and storage of these dopes call for engagement of human labor and require preservation of floor spaces.

In the light of the true state of affairs described above, efforts are directed to decreasing the weight of the dialytic preparation by producing this preparation in the form of powder. JP-B-58-27,246 (1983), for example, discloses as means for uniform dispersion of a liquid acid a method for producing an electrolytic compound powder of the bicarbonate dialysis quality by powder mixing using a microfine powder of sodium chloride acidified with acetic acid. JP-A-62-30,540 (1987), concerning the production of a preparation for dialysis using sodium acetate as a principal component, discloses a technique for decreasing dispersion of the contents of such microconstituents as $MgCl_2 \cdot 6H_2O$ and $CaCl_2 \cdot 2H_2O$ in the dialytic solution obtained from a dialytic preparation having sodium acetate as a principal component by intimately mixing these microconstituents with sodium acetate and water and converting the resultant mixture into fine powder.

EP-A-0 177 614 discloses a preparation for bicarbonate dialysis comprising a mixed powder of electrolytes and acetic acid (composition A) and an aqueous solution of sodium hydrogen carbonate (composition B).

In the powdery preparation for dialysis of the type using sodium hydrogen carbonate as a principal component, calcium chloride and magnesium chloride exhibit a deliquescing property and sodium chloride possibly acquires enhanced hygroscopicity in the presence of calcium chloride and magnesium chloride. This preparation, therefore, undergoes deliquescence or solidification during the course of production, transfer, or storage and entails the disadvantage that it betrays notable dispersion of composition and inferior stability during protracted preservation. Further, since this preparation uses acetic acid as a liquid acid, it possesses a high vapor pressure and readily succumbs to volatilization even when it is adsorbed on an inorganic salt, and lacks stability and workability. In recent years, the practice of curbing possible variation in the blood sugar level by adding glucose to the dialytic solution has been finding acceptance in the field of clinical medicine. None of the preparations heretofore produced for dialysis has proved to be capable of retaining stability in protracted preservation.

An object of this invention, therefore, is to provide a novel powdery preparation for dialysis and a method for the production thereof.

Another object of this invention is to provide a powdery preparation for dialysis, which excels in the ability to withstand the impact of transfer and storage and in the maintenance of uniformity and stability of powder production.

SUMMARY OF THE INVENTION

The objects described above are accomplished by a preparation for blood dialysis, comprising two compositions, i.e. a first powdery composition comprising solid electrolytes for dialysis and a liquid acid and a second powdery composition comprising sodium hydrogen carbonate and glucose.

The present invention discloses a preparation for blood dialysis, wherein the liquid acid is acetic acid. The present invention further discloses a preparation for blood dialysis, wherein the acetic acid has been incorporated by impregnation in a pelletized solid acetate-containing electrolyte for dialysis. The present invention further discloses a preparation for blood dialysis, wherein the preparation, on being dissolved in a prescribed amount of water, produces the following components of solid electrolytes for dialysis and liquid acid from the first composition:

Na^+	90 to 140 mmols
K^+	0 to 4 mmols
Ca^{++}	0.5 to 2.2 mmols
Mg^{++}	0.2 to 1.0 mmol
Cl^-	90 to 140 mmols
CH_3COO^-	6 to 15 mmols

and the following components of sodium hydrogen carbonate and glucose from the second composition:

Na^+	15 to 40 mmols
HCO_3^-	15 to 40 mmols
Glucose	4 to 12 mmols

The present invention further discloses a preparation for blood dialysis, wherein the second solid composition for dialysis is contained in combination with a desiccator such as a moisture absorbent in a moistureproof packing material possessing moisture permeability (20 • C) of not more than 2.0 g/m^2 • 24hrs. The present invention further discloses a preparation for blood dialysis, wherein the first solid composition for dialysis is contained in combination with a desiccator such as a moisture absorbent in a moistureproof packing material possessing moisture permeability (20 • C) of not more than 2.0 g/m^2 • 24hrs.

The objects described above are accomplished by a method for the production of a preparation for blood dialysis, comprising two compositions, i.e. a first powdery composition comprising solid electrolytes for dialysis and a liquid acid and a second powdery composition comprising sodium hydrogen carbonate and glucose, which method is characterized by the fact that the first composition is produced by mixing the components of the solid electrolytes for dialysis, pulverizing and granulating the resultant mixture, and subsequently mixing the resultant granules with the liquid acid.

The objects are further accomplished by a method for the production of a preparation for blood dialysis, comprising two compositions, i.e. a first powdery composition comprising solid electrolytes for dialysis and a liquid acid and a second powdery composition comprising sodium hydrogen carbonate and glucose, which method is characterized by the fact that the first composition is produced by spraying an aqueous solution of the components of the solid electrolytes for dialysis except for sodium chloride into a fluidized bed of sodium chloride powder and, at the same time, granulating the wet sodium chloride powder, and mixing the resultant granules with the liquid acid.

The present invention further discloses a method for the production of a preparation for blood dialysis, wherein the second composition is produced by mixing the powder of glucose, for example, with sodium hydrogen carbonate and subsequently granulating the resultant mixture.

EXPLANATION OF THE PREFERRED EMBODIMENT

The preparation for blood dialysis according with the present invention comprises two compositions, i.e. a first powdery composition comprising solid electrolytes for dialysis and a liquid acid and a second powdery composition comprising sodium hydrogen carbonate and glucose.

The solid electrolytes for dialysis which are usable for the first composition include sodium chloride, potassium chloride, calcium chloride, magnesium chloride, and sodium acetate, for example. The liquid acid is used as a pH-adjusting agent. The liquid acids which are usable for this purpose include acetic acid, lactic acid, and hydrochloric acid, for example. Among other liquid acids mentioned above acetic acid proves to be particularly preferable. This acetic acid is generally adsorbed specifically by the granules of the solid electrolyte for dialysis, particularly by the sodium acetate contained in the granules.

The first composition is preferable, on being dissolved in a prescribed amount of water, to produce the following components of solid electrolytes for dialysis and liquid acid:

Na^+	90 to 140 mmols
K^+	0 to 4 mmols
Ca^{++}	0.5 to 2.2 mmols
Mg^{++}	0.2 to 1.0 mmol
Cl^-	90 to 140 mmols
CH_3COO^-	6 to 15 mmols

preferably:

Na^+	100 to 130 mmols
K^+	1.5 to 3 mmols
Ca^{++}	0.75 to 1.8 mmols
Mg^{++}	0.3 to 0.8 mmol
Cl^-	100 to 130 mmols
CH_3COO^-	8 to 12 mmols

The average particle size of the first composition is in the range of 10 to 200 mesh, preferably 14 to 100 mesh, of standard sieves.

The first composition is preferable to be produced by either the dry method or the fluidized-bed method.

By the dry method, the first composition is obtained by stirring and mixing the solid electrolytes for dialysis with a stirring and mixing device such as a vertical granulator, for example, then pulverizing the mixed solid electrolytes with a pulverizing device such as a pin mill, mixing the pulverized solid electrolytes with a stirring and mixing device such as a vertical granulator, for example, granulating the resultant mixture with a dry granulating device such as a roller compacter, for example, combining the resultant granules with the liquid acid, and mixing them with a stirring and mixing device such as a vertical granulator or a Nauter mixer, for example.

By the fluidized-bed method, the first composition is obtained by dissolving the solid electrolytes for dialysis other than sodium chloride in water of an amount 0.8 to 30 times, preferably 1.5 to 15 times, the amount of the solid electrolytes, spraying the resultant aqueous solution into a fluidized bed formed of sodium chloride powder inside a fluidized-bed granulating device and, at the same time, granulating the wet powder, combining the resultant granules with the liquid acid, and mixing them with a stirring and mixing device such as a vertical granulator or a Nauter mixer, for example.

The second composition is a powdery composition comprising sodium hydrogen carbonate and glucose. When this second composition is dissolved in a prescribed amount of water, the components thereof, i.e. sodium hydrogen carbonate and glucose produce 15 to 40 mmols of Na^+, 15 to 40 mmols of HCO_3^-, and 4 to 12 mmols of glucose, preferably 20 to 27 mmols of Na^+, 20 to 27 mmols of HCO_3^-, and 6 to 10 mmols of glucose. The average particle size of the second composition is in the range of 10 to 100 mesh, preferably 12 to 100 mesh, of standard sieves.

The second composition is obtained by pulverizing glucose with a pulverizing device such as a pin mill, for example, mixing the pulverized glucose with sodium hydrogen carbonate powder in a stirring and mixing device such as a vertical granulator, for example, and subsequently granulating the resultant mixture in a

dry granulating device such as a roller compacter, for example.

The first and second compositions which are produced as described above are placed in separate containers. Prior to use, these compositions are dissolved in water and the resultant aqueous solution is supplied to the artificial kidney, there to be used as a liquid for blood dialysis.

The packing material to be used for containing these compositions is preferably to possess low moisture permeability. It is preferable, for example, to use a moistureproof packing material possessing moisture permeability (20°C) of not more than 2.0 g/m^2•24hrs. As one packing material fulfilling this requirement, there may be cited a laminate film which is obtained by superposing polyethylene terephthalate/polyethylene/aluminum foil/polyethylene layers measuring 12 μm, 15 μm, 7 μm, and 30 μm respectively in thickness (moisture permeability 0.1 g/m^2•24hrs). The first and second compositions are preferably to be each contained in a packing material in combination with an air-permeability container filled with a desiccant such as silica gel, a synthetic zeolite type moisture absorbent, or a calcium carbonate type moisture absorbent, for example.

Now, the present invention will be described more specifically below with reference to working examples. Wherever the term "parts" is used in the working examples, it is meant as "parts by weight" unless otherwise specified.

Example 1

In a vertical granulator (stirring and mixing device produced by Fuji Sangyo K.K. and marketed under product code of "VG-25P"), 2188.7 parts of sodium chloride, 52.2 parts of potassium chloride, 77.2 parts of calcium chloride [$CaCl_2 \cdot 2H_2O$], 35.6 parts of magnesium chloride [$MgCl_2 \cdot 6H_2O$], and 215.2 parts of sodium acetate [$CH_3COONa \cdot 3H_2O$] were mixed by stirring. The resultant mixture was pulverized with a pin mill (pulverizer produced by Fuji Sangyo K.K. and marketed under trademark designation of "Kollplex 16Z") and further mixed by stirring with the vertical granulator. The mixture thus produced was pelletized with a roller compacter (dry pelletizer produced by Turbo Kogyo K.K. and marketed under product code of "WP-160X60"). The granules consequently obtained and 41.5 parts of acetic acid added thereto were mixed by stirring with the vertical granulator. The first composition obtained as the result was found to have a particle size distribution as follows.

Mesh	%
-12	0.15
12-32	44.59
32-48	16.09
48-80	8.00
80-150	5.27
150-	25.89
Average particle diameter	32-48 meshes

Example 2

An aqueous solution was obtained by dissolving 52.2 parts of potassium chloride, 77.2 parts of calcium chloride [$CaCl_2 \cdot 2H_2O$], 35.6 parts of magnesium chloride [$MgCl_2 \cdot 6H_2O$], and 357.2 parts of sodium acetate [$CH_3COONa \cdot 3H_2O$] in 1,500 parts (about 3 times the amount of electrolytes) of water. Inside a fluidized-bed pelletizer (produced by Fuji Sangyo K.K. and marketed under product code of "STREA-15"), 2188.7 parts of sodium chloride was fluidized and the fluidized bed of sodium chloride was sprayed with the aqueous solution mentioned above to gain in weight. The granules thus obtained were placed in the vertical granulator and were mixed by stirring with 41.5 parts of acetic acid added thereto. The first composition thus obtained was found to have a particle size distribution as follows.

Mesh	%
-12	0.07
12-32	5.44
32-48	6.22
48-80	24.51
80-150	48.64
150-	15.08
Average particle diameter	80-150 meshes

Example 3

In a pin mill, 525 parts of glucose was pulverized. The powder thus obtained was placed in the vertical granulator and were mixed by stirring with 750 parts of sodium hydrogen carbonate. The resultant mixture was pelletized with a roller compacter. The second composition consequently obtained was found to have a particle diameter distribution as follows.

Mesh	%
-12	10.44
12-32	53.20
32-48	6.17
48-80	3.29
80-150	2.71
150-	24.19
Average particle diameter	12-32 meshes

Example 4

The first and second composition obtained in Examples 2 and 3 were separately placed in bags of a laminate film obtained by superposing polyethylene terephthalate (12 μm), polyethylene (15 μm), aluminum foil (7 μm), and polyethylene (30 μm) layers without use of any desiccant and tested for stability in storage at 40 °C. The results were as shown in Table 1.

Table 1

Item	0 month	1 month	2 months
First composition			
Color difference (ΔE)	0.00	0.13	0.12
Residual ratio of acetic acid ion (%)	100.0	102.4	100.7
Occurrence of aggregation		Yes	Yes
Second composition			
Color difference (ΔE)	0.00	1.28	2.36
Occurrence of aggregation		Yes	Yes

The "color difference (ΔE)" represents the numerical value (absolute number) determined by the use of a colorimetric system (produced by Minolta Camera K.K. and marketed under product code of "CD-200"). The "residual ratio of acetic acid ion" represents the magnitude determined by dissolving part of a sample in water and examining the resultant aqueous solution by high-speed liquid chromatography (by the use of a system produced by Nippon Bunko K.K. and marketed under product code of "BIP-I").

Example 5

The first and second compositions obtained in Examples 2 and 3 were separately placed in combination with silica gel as a desiccant in bags made of a laminate film obtained by superposing polyethylene terephthalate (12 μm), polyethylene (15 μm), aluminum foil (7 μm), and polyethylene (30 μm) layers and tested for stability in storage at 40 • C. The results were as shown in Table 2.

Table 2

Item	0 month	1 month	2 months
First composition			
Color difference (ΔE)	0.00	0.12	0.12
Residual ratio of acetic acid ion (%)	100.0	101.4	100.5
Occurrence of aggregation		No	No
Second composition			
Color difference (ΔE)	0.00	0.12	0.06
Occurrence of aggregation		No	No

Example 6

The first composition obtained in Example 1, a composition produced by following the procedure of Example 1, except that the addition of sodium acetate was omitted (composition of Control 1), and a mixture of 2188.7 g of sodium chloride and 41.5 g of acetic acid (composition of Control 2) were left standing in the open air at 30 • C for 30 minutes and then analyzed to determine the residual ratio of acetic acid. The results were as shown in Table 3.

Table 3

Time	Composition		
	Example 1	Control 1	Control 2
Immediately after production	100%	100%	100%
After 30 minutes following production	99.8%	21.3%	12.7%

It is clearly noted from Table 3 that the preparations for blood dialysis according with the present invention show specific adsorption of acetic acid by sodium acetate and excel in stability in preservation.

Example 7 (comparative example)

An aqueous solution was obtained by dissolving 52.2 parts of potassium chloride, 77.2 parts of calcium chloride [$CaCl_2 \cdot 2H_2O$], 35.6 parts of magnesium chloride [$MgCl_2 \cdot 6H_2O$], 357.2 parts of sodium acetate [$CH_3COONa \cdot 3H_2O$] in water of an amount 5 times the amount of the inorganic salts. Separately, granules obtained by mixing and stirring 2188.7 parts of sodium chloride and 525 parts of glucose with the vertical granulator were fluidized within a fluidized-bed pelletizer (produced by Fuji Sangyo K.K. and marketed under product code of "STREA-15") and the fluidized bed of the granules was sprayed with the aforementioned aqueous solution to gain in weight. The granules thus obtained were placed in the vertical granulator and were then mixed by stirring with 41.5 parts of acetic acid added thereto. The first composition consequently obtained was found to have a particle size distribution as follows.

Mesh	%
-12	1.20
12-32	10.23
32-48	17.21
48-80	40.32
80-150	26.87
150-	4.17
Average particle diameter	40-80 meshes

The first composition so obtained was placed, as not accompanied with any desiccator, in a bag made of a laminate film obtained by superposing polyethylene terephthalate (12 μm), polyethylene (15 μm), aluminum foil (7 μm), and polyethylene (30 μm) layers and tested for stability in storage at 40 • C. The results were as shown in Table 4.

Table 4

Item	0 month	1 month	2 months
Color difference (ΔE)	0.00	9.77	14.99
Residual ratio of acetic acid ion (%)	100.0	98.9	98.9
Occurrence of aggregation		Yes	Yes

The "color difference (ΔE)" represents the numerical value (absolute number) determined by the use of a colorimetric system (produced by Minolta Camera K.K. and marketed under product code of "CD-200"). The "residual ratio of acetic acid ion" represents the magnitude determined by dissolving part of a sample in water and examining the resultant aqueous solution by high-speed liquid chromatography (by the use of a system produced by Nippon Bunko K.K. and marketed under product code of "BIP-I").

The preparation for blood dialysis according with the present invention, as described above, comprises two compositions, i.e. a first powdery composition comprising solid electrolytes for dialysis and a liquid acid and a second powdery composition comprising sodium hydrogen carbonate and glucose. It is, therefore, notably light as compared with the conventional dialytic liquid. When acetic acid is used as the liquid acid meant as a pH-adjusting agent, the preparation enjoys the advantage that it exhibits highly satisfactory stability in protracted preservation because the acetic acid impregnates the solid electrolyte particles containing the aforementioned acetate.

It has been found incredibly that the stability of the preparation is invariably high when sodium chloride is incorporated in the first composition or in the second composition. This freedom as to the incorporation of the sodium chloride allows the contents of sodium chloride in the first composition and the second composition to approximate to each other to the greatest possible extent and obviates the necessity for using different devices in dissolving the two compositions of the preparation. Thus, the prevent invention contributes to simplifying the equipment required in putting the preparation to use.

The preparation for blood dialysis according with the present invention is produced by the dry method or the fluidized-bed method. In spite of the use of calcium chloride or magnesium chloride, a substance which has heretofore defied uniform pulverization because of an excessively high deliquescing property, the powdery compositions of the preparation can be homogenized. Further, the problem that the components of the compositions cannot be easily distributed uniformly can be precluded by the aforementioned method of production.

Claims

1. A preparation for blood dialysis comprising two compositions, i.e. a first powdery composition comprising solid electrolytes for dialysis and a liquid acid and a second powdery composition comprising sodium hydrogen carbonate and glucose.

2. The preparation according to claim 1, wherein said liquid acid is acetic acid.

3. The preparation according to claim 2, wherein said acetic acid has impregnated granules of said solid electrolytes for dialysis containing an acetate.

4. The preparation according to any one of claims 1 - 3, wherein said preparation contains, on being dissolved in a prescribed amount of water, the following components of said solid electrolytes for dialysis and liquid acid from said first composition :

Na^+	90 to 140 mmols
K^+	0 to 4 mmols
Ca^{++}	0.5 to 2.2 mmols
Mg^{++}	0.2 to 1.0 mmol
Cl^-	90 to 140 mmols
CH_3COO^-	6 to 15 mmols

and the following components of sodium hydrogen carbonate and glucose from said second composition :

Na^+	15 to 40 mmols
HCO_3^-	15 to 40 mmols
Glucose	4 to 12 mmols

5. The preparation according to any one of claims 1 - 4, wherein said second powdery composition is contained in combination with a dessicant such as a moisture absorbent in a moistureproof packing material having a moisture permeability (20 • C) of not more than 2.0 g/m²•24hrs.

6. The preparation according to any one of claims 1 - 5, wherein said first powdery composition is contained in combination with a dessicant such as a moisture absorbent in a moistureproof packing material having a moisture permeability (20 • C) of not more than 2.0 g/m²•24hrs.

7. A method for the production of a preparation for blood dialysis as defined in any one of claims 1-6, which method comprises preparing said first composition by mixing the components of said solid electrolytes for dialysis, pulverizing and then granulating the resultant mixture, and then mixing the resultant granules with said liquid acid.

8. A method for the production of a preparation for blood dialysis as defined in any one of claims 1-6, which method comprises preparing said first composition by spraying an aqueous solution of the components of said solid electrolytes for dialysis other than sodium chloride into a fluidized bed formed of sodium chloride powder and, at the same time, granulating the wet sodium chloride powder, and mixing the resultant granules with said liquid acid.

9. A method according to claim 7 or claim 8, wherein said second composition is produced by mixing the powder of glucose with sodium hydrogen carbonate and subsequently granulating the resulting mixture.

Patentansprüche

1. Präparat zur Blutdialyse, umfassend zwei Zubereitungen, d.h. eine erste pulverförmige Zubereitung mit festen Elektrolyten für die Dialyse und einer flüssigen Säure und eine zweite pulverförmige Zubereitung mit Natriumhydrogencarbonat und Glucose.

2. Präparat nach Anspruch 1, wobei die flüssige Säure aus Essigsäure besteht.

3. Präparat nach Anspruch 2, wobei die Essigsäure in ein ein Acetat enthaltendes Granulat der festen Elektrolyte für die Dialyse imprägniert ist.

4. Präparat nach einem der Ansprüche 1 bis 3, welches nach dem Auflösen in einer vorgeschriebenen Menge Wasser folgende Komponenten der festen Elektrolyte für die Dialyse und der flüssigen Säure (aus der ersten Zubereitung):

Na^+	90 bis 140 mmol
K^+	0 bis 4 mmol
Ca^{++}	0,5 bis 2,2 mmol
Mg^{++}	0,2 bis 1,0 mmol
Cl^-	90 bis 140 mmol
CH_3COO^-	6 bis 15 mmol

und die folgenden Komponenten von Natriumhydrogencarbonat und Glucose (aus der zweiten Zubereitung):

Na^+	15 bis 40 mmol
HCO_3^-	15 bis 40 mmol
Glucose	4 bis 12 mmol

enthält.

5. Präparat nach einem der Ansprüche 1 bis 4, wobei die zweite pulverförmige Zubereitung in Kombination mit einem Trocknungsmittel, z.B. einem Feuchtigkeit absorbierenden Mittel, in einem feuchtigkeitsdichten Verpackungsmaterial einer Feuchtigkeitsdurchlässigkeit (20 °C) von nicht mehr als 2,0 $g/m^2 \cdot 24h$ enthalten ist.

6. Präparat nach einem der Ansprüche 1 bis 5, wobei die erste pulverförmige Zubereitung in Kombination mit einem Trocknungsmittel, z.B. einem Feuchtigkeit absorbierenden Mittel, in einem feuchtigkeitsdichten Verpackungsmaterial einer Feuchtigkeitsdurchlässigkeit (20 °C) von nicht mehr als 2,0 $g/m^2 \cdot 24h$ enthalten ist.

7. Verfahren zur Herstellung eines Präparats zur Blutdialyse nach einem der Ansprüche 1 bis 6 durch Herstellen der ersten Zubereitung durch Vermischen der Komponenten der festen Elektrolyte für die Dialyse, Pulverisieren und anschließendes Granulieren des erhaltenen Gemischs und anschließendes Vermischen des erhaltenen Granulats mit der flüssigen Säure.

8. Verfahren zur Herstellung eines Präparats zur Blutdialyse nach einem der Ansprüche 1 bis 6 durch Herstellen der ersten Zubereitung durch Aufsprühen einer wäßrigen Lösung der Komponenten der festen Elektrolyte für die Dialyse mit der Ausnahme von Natriumchlorid auf ein aus Natriumchlorid gebildetes Wirbelbett und gleichzeitig Granulieren des feuchten Natriumchloridpulvers und anschließendes Vermischen des erhaltenen Granulats mit der flüssigen Säure.

9. Verfahren nach Anspruch 7 oder 8, wobei die zweite Zubereitung durch Vermischen von Glucosepulver mit Natriumhydrogencarbonat und anschließendes Granulieren des erhaltenen Gemischs hergestellt wird.

Revendications

1. Préparation pour hémodialyse comprenant deux compositions, à savoir une première composition pulvérulente comprenant des électrolytes solides pour dialyse et un acide liquide et une seconde composition pulvérulente comprenant de l'hydrogénocarbonate de sodium et du glucose.

2. Préparation selon la revendication 1, dans laquelle ledit acide liquide est de l'acide acétique.

3. Préparation selon la revendication 2, dans laquelle ledit acide acétique a imprégné des granules desdits électrolytes solides pour dialyse contenant un acétate.

4. Préparation selon l'une quelconque des revendications 1 à 3, dans laquelle ladite préparation contient, lors de sa dissolution dans une quantité prescrite d'eau, les composants suivants desdits électrolytes solides pour dialyse et de l'acide liquide de ladite première composition :

Na^+	90 à 140 mmol
K^+	0 à 4 mmol
Ca^{++}	0,5 à 2,2 mmol
Mg^{++}	0,2 à 1,0 mmol
Cl^-	90 à 140 mmol
CH_3COO-	6 à 15 mmol

et les composants suivants, de l'hydrogénocarbonate de sodium et du glucose de ladite seconde composition :

Na^+	15 à 40 mmol
HCO_3^-	15 à 40 mmol
Glucose	4 à 12 mmol

5. Préparation selon l'une quelconque des revendications 1 à 4, dans laquelle ladite seconde composition pulvérulente est contenue en association avec un déshydratant tel qu'un absorbant d'humidité dans un matériau d'emballage résistant à l'humidité, ayant une perméabilité à l'humidité (20 • C) inférieure ou égale à 2,0 g/m².24 h.

6. Préparation selon l'une quelconque des revendications 1 à 5, dans laquelle ladite première composition pulvérulente est contenue en association avec un déshydratant tel qu'un absorbant d'humidité dans un matériau d'emballage résistant à l'humidité, ayant une perméabilité à l'humidité (20 • C) inférieure ou égale à 2,0 g/m².24 h.

7. Procédé de production d'une préparation pour hémodialyse selon l'une quelconque des revendications 1 à 6, lequel procédé comprend la préparation de ladite première composition par mélange des composants desdits électrolytes solides pour dialyse, pulvérisation, puis granulation du mélange obtenu et ensuite mélange des granules obtenus avec ledit acide liquide.

8. Procédé de production d'une préparation pour hémodialyse selon l'une quelconque des revendications 1 à 6, lequel procédé comprend la préparation de ladite première composition par pulvérisation d'une solution aqueuse des composants desdits électrolytes solides pour dialyse autres que le chlorure de sodium dans un lit fluidisé formé de poudre de chlorure de sodium et granulation simultanée de la poudre humide de chlorure de sodium, et mélange des granules obtenus avec ledit acide liquide

9. Procédé selon la revendication 7 ou la revendication 8, dans lequel ladite seconde composition est produite par mélange de la poudre de glucose avec de l'hydrogénocarbonate de sodium et granulation subséquente du mélange obtenu.